United States Department of Agriculture
Food Safety And Inspection Service
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AUDIT REPORT FOR HUNGARY

FEBRUARY 8 THROUGH FEBRUARY 18, 2000

January 9, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Hungary's meat inspection system from February 8 through February 18, 2000. Six of the nine establishments certified to export meat to the United States were audited. Five of these were slaughter establishments; the other one was conducting processing operations.

The last audit of the Hungarian meat inspection system was conducted in March 15, 1999. Nine establishments were audited: six (Ests. 5, 7, 10, 24, 46, and 62) were acceptable; three (Ests. 6, 64, and 147) were evaluated as acceptable/re-review. No system failure was reported at that time. During this new audit (three of these establishments 6, 64, and 147, were included in the new itinerary) implementation of the required HACCP programs was found to be deficient in all nine (Ests. 6, 7, 10, 24, 64, 147, 5, 46, and 62) establishments visited.

The following were major deficiencies from the previous audit:

1. The written SSOPs procedures for pre-operational and operational sanitation were not separately described in Establishments 5, and 10.
   Corrected.

2. The corrective actions taken for identified daily pre-operational and operational SSOPs deficiencies were not adequately described in Establishment 62.
   Corrected

3. Establishment 7- SSOP was in the HACCP plan as a CCP.
   Corrected.

4. The established frequency of SSOP was not documented in the written program in Establishment 147.
   Corrected.

5. The written *E. coli* testing program in Eetablishment 62, was incomplete.
   Corrected.

6. Establishment 64- *E. coli* testing was part of SSOP rather than part of HACCP program. *Corrected.*
7. The pest control program in Establishment 5 did not properly record the presence of rodents and Establishment 6 did not perform rodent control during the week. *Corrected.*

8. Establishments 6, 64, and 147- fecal matter and bile on carcasses indicating incorrect sanitary dressing procedures. *Corrected.*

9. The equipment used for dressing procedures was not being sanitized properly in the slaughter room in Establishments 6, 7, and 24. In Establishment 62, the sanitizer temperature was not being maintained at 180º F.
   Establishments officials took corrective actions immediately and preventive measures were proposed to GOH officials.

10. Cross contamination of carcasses by contacting with adjacent carcasses at the stunning area in Establishments 6, 7, and 64.
    Corrected.

11. Water dripping from pipes into the empty, washed cans (before filling) in Establishment 64; flaking paint hanging over exposed product in Establishment 64, and on carcasses in Establishment 7.
    Corrected.

12. Establishment 10 – ante-mortem could not be performed properly due to overcrowded pens.
    Corrected.

13. Establishment 6 – suspect carcasses were contacting other suspected carcasses on the suspect line.
    Corrected.

14. Establishment 62 – inadequate stunning facilities.
    This discrepancy has been corrected as records indicated.

15. All establishments that slaughter more than one type of livestock are being tested for generic *E. coli,* not just predominant species.
    E. coli testing criteria was explained to GOH officials, such as swine and cattle slaughtered in the greatest number shall be tested.

16. Establishments 6, 24, 62, and 64 – improper trimming of blood clots and bruises. *Corrected except Establishment 62. This was observed during record evaluations.*

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Hungarian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. Establishments 7, 10, and 24 were selected randomly and Establishments 6, 64, and 147, evaluated as acceptable/re-review in the previous audit, were included for-on-site audits. Establishments 5, 46, and 62 were selected randomly for records evaluations only. The third part was conducted by on-site visits to establishments. The fourth was a visit to one laboratory, performing analytical testing of field samples for the

national residue testing program, and culturing field samples for the presence of microbiological contamination with *Salmonella*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Hungary's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Based on the performance of the individual establishments, Hungary's "In-Plant Inspection System Performance" was evaluated as In-Plant System Controls In Place.

Effective inspection system controls were found to be in place in all of the six establishments audited. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

As stated above, fifteen major concerns had been identified during the last audit of the Hungarian meat inspection system, conducted in March, 1999. During this new audit, the auditor determined that all major deficiencies had been addressed and corrected.

During this new audit, implementation of the required HACCP programs was found to be deficient in the six establishments visited (Ests. 6, 7, 10, 24, 64, and 147), and the three establishments (Ests. 5, 46, and 62) selected for records audits. Details are provided in the Slaughter/ Processing Controls section later in this report.

Entrance Meeting

On February 9, an entrance meeting was held at the Ministry of Agriculture in Budapest, and was attended by Dr. Tibor Balint, Chief Veterinary officer, Animal Health and Food Control Department, Ministry of Agriculture and Regional Development; Dr. Kalman Szekely, Head of Department of Food Control; Dr. Rayda Imre, Head of Division, National Food Investigating Institute(NFII); Dr. Sandor Tili, Head of Export Department, NFII; Dr. Veronica Olah, Senior

Veterinary Officer, NFII; Mr. Paul Spencer-MacGregor, Agricultural Attache, U.S. Embassy in Vienna, Austria and Dr. Faizur Choudry, International Audit Staff Officer. Topics of discussion included the following:

1. Updates on the inspection system of Hungary

2. The audit itinerary and travel arrangements

3. The U.S.-EC Veterinary Agreement issue

4. Delistment issues

5. Generic *E. coli, Salmonella* testing.

6. HACCP implementation

7. SSOP implementation

8. Residue Questionnaire, Test Results (1999) and plans (2000)

9. Species Testing Policy

10 Enforcement – *Salmonella/*routine, Enforcement Report, Criminal Prosecution.

11. *Listeria Monocytogenes.* A) Do establishments' HACCP plans provide for control of *Listeria Monocytogenes*? B) If not, did the establishments have substantial scientific evidence to demonstrate that controls are not needed? C) Do the establishments take corrective actions as necessary?

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Hungary's inspection system in March 1999.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the Ministry of Agriculture in Budapest. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.

- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

The following concerns arose as a result the examination of these documents.

1. Establishment 6 was sponging carcasses for *E. coli* sampling, while it was using excising samples criteria (m, M) for the evaluation of test results. Establishments sponging carcasses are to evaluate *E. coli* test results using a statistical process control technique. GOH and establishment officials agreed to correct this deviation.

2. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed. Neither establishment nor GOH inspection officials were performing adequate ongoing verification activities of HACCP program, in all establishments.

3. Monitoring frequencies and corrective actions to be followed in response to a deviation from a critical limit are not addressed adequately in the written HACCP plan in all establishments audited.

4. The zero-tolerance policy for visible fecal material on carcasses was not enforced by either establishment or GOH inspection officials, and no monitoring record was maintained to verify this activity, except in Establishment 147.

5. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of the product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail. GOH meat inspection officials indicated they would implement this requirement promptly.

6. Cross-contamination of product: blood and fat were found on the automatic viscera and offal conveyors after washing/sanitizing during operation in the slaughter rooms in Establishments 6 and 7. These deficiencies had also been identified during the last FSIS audit and had not been satisfactorily addressed and corrected.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Hungary as eligible to export meat products to the United States were full-time government employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Nine establishments were certified to export meat products to the United States at the time this audit was conducted. Six (Ests. 6, 7, 10, 24, 64, and 147) establishments were visited for on-site audits. In all of the six establishments visited, both GOH inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The National Food Investigation Institute Laboratory in Budapest was audited on February 18, 2000. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recovery, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done.

The check sample program met FSIS requirements but analytical results were not signed and dated by the analyst and by the supervisor. Officials agreed to correct this issue immediately.

Hungary's microbiological testing for *Salmonella* was being performed in the National Food Investigation Institute laboratory in Budapest was audited.

Establishment Operations by Establishment Number

The following operations were being conducted in the six establishments that were visited for on-site audits:

Establishments 6 – slaughter cattle, hogs and boning, cutting, cured/dried/smoked products, non-shelf stable canned product, and edible rendering.

Establishment 7 – slaughter cattle, hogs and boning, cutting, cured/dried/smoked products, and edible rendering.
Establishment 10 – slaughter hogs and boning, cutting, cured/dried/smoked products, non-shelf stable canned products.
Establishment 24 – slaughter cattle, hogs and boning, cutting.
Establishment 64 – slaughter cattle, hogs and boning, cutting, cured/dried/smoked products, shelf stable and non-shelf stable canned products, and edible rendering.
Establishment 147 – boning, cutting, and cured/dried/smoked products and non-shelf stable canned products.

The following operations were being conducted in the three establishments that were selected for document audits:

Establishment 5 – slaughter hogs and boning, cutting, cured/dried/smoked products.
Establishment 46 – slaughter hogs and boning, cutting.
Establishment 62 – slaughter hogs and boning, cutting, and cured/dried/smoked products.

SANITATION CONTROLS

Based on the on-site audits of establishments, Hungary's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest control and monitoring; temperature control; lighting; work space; ventilation; maintenance and cleaning of over- product ceilings and equipment; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; and product handling and storage.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The Sanitation Standard Operating Procedures (SSOPs) were audited and found to meet the basic FSIS regulatory requirements, with only occasional minor or major variations.

GOH meat inspection officials were recording their findings on the establishments' records for the SSOPs monitoring program in Establishment 10, rather keeping their own records independently.

Cross-Contamination

1. Blood and fat were found on the automatic hog viscera and offal hook conveyors after washing/sanitizing in the slaughter room in Establishment 7. Blood and fat were found on the automatic viscera conveyor after washing/sanitizing in the slaughter room in

Establishment 6. Both Establishment officials took corrective actions immediately and proposed preventive measures to GOH officials.
These deficiencies had been identified during the last audit.

2. Hand washing basin was clogged and overflowing at the hog belly opening station in Establishments 6, and 7. Officials in both establishments took corrective actions immediately.

3. Hog carcasses were contacting work platform and employees' boots at the carcass marking/branding station in Establishment 64. Establishment officials took corrective actions immediately and proposed preventive measures to GOH officials.

Basic Establishment Facilities

1. Gaps at the bottoms of door were not sealed properly to prevent the entrance of rodents and other vermin in the slaughter room and processing room in Establishment 6. No evidence of pests was observed. Establishment officials proposed preventive measures.

2. Gaps at the bottoms of door were not sealed properly to prevent the entrance of rodents and other vermin in the dry storage room and spice room in Establishment 64. No evidence of pests was observed. Establishment officials proposed preventive measures.

Condition of Facilities and Equipment

Numerous metal edible product containers were cracked and damaged in the boning and processing rooms in Establishment 64. Establishment officials ordered immediate correction and proposed preventive measures to GOH officials.

ANIMAL DISEASE CONTROLS

Hungary's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. In Hungary hog cholera (Classical Swine Fever) has not been reported positive since May 1993. No positive case of Bovine Spongiform Encephalopathy (BSE) was reported in Hungary.

Product was cooked at a minimum 70º C and product was cured and dried at least 90 days as required by APHIS.

RESIDUE CONTROLS

Hungary's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Hungarian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals

SLAUGHTER/PROCESSING CONTROLS

The Hungarian inspection system had controls in place to ensure adequate animal identification; antemortem inspection procedures; antemortem dispositions; humane slaughter; postmortem inspection procedures; postmortem dispositions; condemned product control; restricted product control; pre-boning trim; boneless meat reinspection; ingredients identification; control of restricted ingredients; formulations; packaging materials; inspector monitoring; processing schedules; processing equipment and records; empty can inspection and filling procedures; container closure examination; post-processing handling; incubation procedures; processing defect action-plant; and processing control-inspection.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements with the following exceptions:

1. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed. Neither establishment personnel nor GOH inspection officials were performing adequate ongoing verification activities of HACCP program in all establishments audited.

2. Monitoring frequencies and corrective actions to be followed in response to a deviation from a critical limit are not addressed adequately in the written HACCP plan in all establishments audited.

3. The zero-tolerance policy for visible fecal material on carcasses was not enforced by either establishment or GOH inspection officials, and no monitoring record was maintained to verify this activity, except in Establishment 147.

4. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper

disposition of the product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail. GOH meat inspection officials indicated to implement this requirement promptly.

GOH inspection and establishment officials agreed to take corrective actions for the discrepancies identified in their HACCP programs.

Testing for Generic *E. coli*

Hungary has adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following equivalent different requirements:

LABORATORIES. Government laboratories. The criteria used for equivalence decisions for use of government laboratories in lieu of private laboratories are:

- The laboratory has properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record keeping facilities.

- Results of analyses including all permanently recorded data and summaries were reported promptly to the establishment.

Six of the establishments audited on-site and three for records audits were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements with the only variation in Establishment 6, where the method for sponging carcasses for *E. coli* sampling was used, while excision samples criteria was being used for the evaluation of test results.

Establishment officials indicated that they would take corrective action immediately to comply with this requirement.

Additionally, establishments had adequate controls in place to prevent meat products intended for Hungarian domestic consumption from being commingled with products eligible for export to the U.S.

Listeria monocytogenes

1. The control of *Listeria monocytogenes* is not included in the HACCP plan in any establishment.
2. None of the establishments had scientific evidence to demonstrate that controls are not needed.
3. GOH inspection service had a surveillance program for *Listeria monocytogenes* testing (one sample per month) for heat-treated products only.

ENFORCEMENT CONTROLS

Inspection System Controls

The GOH inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, and the importation of only eligible meat products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

All of the six establishments audited on-site and the three establishments audited for records were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The *Salmonella* testing programs was audited and found to meet the basic FSIS regulatory requirements.

GOH meat inspection service has implemented *Salmonella* testing (one sample per month for beef and pork carcasses).

GOH inspection service has a regulation to enforce noncompliance when they determine that an establishment has not met the *Salmonella* standard. GOH inspection service uses Veterinary Police throughout the chain of distribution to detect and detain potentially hazardous foods in commerce to prevent their consumption and to investigate violations of law. Hungary's equivalent of FSIS Regulatory and Enforcement Division. There are experienced veterinarians assigned in each District Office.

Species Verification Testing

At the time of this audit, Hungary was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed by each Chief of County Veterinarian, Hungary's equivalent of an Area Supervisor.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were both announced in advance and not announced, and were conducted, at times, by individuals, and at other times by a team of reviewers including a veterinarian from the State, at least once monthly. The records of audited establishments were kept in the inspection offices of the individual establishments and at the office of the County Veterinarian.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, it is delisted for U.S. export. Before it may again qualify for eligibility to be reinstated, a commission is empowered to conduct an in-depth review, and the results are reported to Dr. Tibor Balint, Chief Veterinary officer and Dr. Imre Rayda, Head of the Division for evaluation. They formulate a plan for corrective actions and preventive measures.

After observing the internal reviewers' activities in the field, the auditor was confident in their professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Hungary's internal review program as a whole.

Enforcement Activities

Controls were in place to ensure adequate export product identification, inspector verification, export certificates, a single standard of control throughout the establishments, inspection supervision as required, and adequate controls for security items, shipment security, species verification, and products entering the establishments from outside sources.

Dr. Tibor Balint, Chief Veterinary Officer, indicated that they had a regulation to enforce noncompliance when they determine that an establishment has not met the *Salmonella* standard. GOH inspection service uses Veterinary Police throughout the chain of distribution to detect and detain potentially hazardous foods in commerce to prevent their consumption and to investigate violations of law. Hungary's Veterinary Police is equivalent of FSIS Regulatory and Enforcement Division. They are experienced veterinarians assigned in each District Office.

GOH meat inspection officials stated that Veterinary Police investigation reports were not readily available.

Exit Meetings

An exit meeting was conducted at the Ministry of Agriculture in Budapest on February 18, 2000. The Hungarian participants were Dr. Tibor balint, Chief Veterinary Officer; Dr. Agnes Horvath, Junior Expert, EU Harmonisation Working Group on Veterinary Issues, Department of Animal Health and Food Control; Dr. Eckhart Brigitta, Food Hygiene specialist; Dr. Imre Rayda, Head of Division, NFII; Dr. Sandor Tili, Head of Export Department, NFII; Dr. Veronica Olah, Senior

Veterinary Officer, NFII; Dr. Ferenc Nemes, Agricultural Specialist, Embassy of the United States of America in Budapest and Dr. Faizur R. Choudry, International Audit Staff Officer. The individual audit findings including HACCP program, as enumerated in the body of this report. The Hungarian officials agreed to take the necessary steps to ensure that corrective actions and preventive measures, as promised during the audits and exit meetings in the individual establishments, would be implemented.

The following deficiencies were discussed:

1. Establishment 6 was sponging carcasses for *E. coli* sampling, while it was using excising samples criteria (m, M) for the evaluation of test results. Establishments sponging carcasses are to evaluate *E. coli* test results using a statistical process control technique. GOH and establishment officials agreed to correct this deviation.

2. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed. Neither establishment nor GOH inspection officials were performing adequate ongoing verification activities of HACCP program, in all the establishments.

3. Monitoring frequencies and corrective actions to be followed in response to a deviation from a critical limit are not addressed adequately in the written HACCP plan in all establishments audited.

4. The zero-tolerance policy for visible fecal material on carcass was not enforced by either establishment or GOH inspection officials, and no monitoring record was maintained to verify this activity, except in Establishment 147.

5. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of the product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail and AHFCD meat inspection officials indicated to implement this requirement promptly.

6. Cross-contamination of product: blood and fat were found on the automatic viscera and offal conveyors after washing/sanitizing during operation in the slaughter rooms in Establishments 6 and 7. These deficiencies had also been identified during the last FSIS audit and had not been satisfactorily addressed and corrected.

CONCLUSION

The inspection system of Hungary was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments with the following exceptions. Six establishments were audited and all were acceptable. The deficiencies encountered during the on-site establishment reviews were adequately addressed to the auditor's satisfaction. The AHFCD

inspection officials reinforced the assurances made by field personnel during and at the conclusions of the on-site audits of the establishments, and stated that they would ensure prompt compliance.

The major deficiencies were the following:

1. Establishment 6 was sponging carcasses for *E. coli* sampling, while it was using excising samples criteria (m, M) for the evaluation of test results. GOH and establishment officials agreed to correct this deviation.

2. The HACCP plans did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed.

3. Monitoring frequencies and corrective actions to be followed in response to a deviation from a critical limit are not addressed adequately in the written HACCP plans in all establishments audited.

4. The zero-tolerance policy for visible fecal material on carcass was not enforced by either establishment or GOH inspection officials, except in Establishment 147.

5. Both establishment and inspection personnel had been unaware of the requirement for a final review of all documentation pertaining to the monitoring of critical limits for the product included in each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail and AHFCD inspection officials indicated to implement this requirement promptly.

6. Cross-contamination of product: blood and fat were found on the automatic viscera and offal conveyors after washing/sanitizing during operation in the slaughter rooms in Establishments 6 and 7. These deficiencies had also been identified during the last FSIS audit and had not been satisfactorily addressed and corrected.

Dr. Faizur R. Choudry (Signed) *Dr. Faizur R. Choudry*
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used included the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. Sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. Identified	7. Docu-mentation done daily	8. Dated and signed
6	√	√	√	√	√	√	√	√
7	√	√	√	√	√	√	√	√
10	√	√	√	√	√	√	√	√
24	√	√	√	√	√	√	√	√
64	√	√	√	√	√	√	√	√
147	√	√	√	√	√	√	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. Sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. Identified	7. Docu-mentation done daily	8. Dated and signed
5	√	√	√	√	√	√	√	√
46	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. TIF-119) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or does not include records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. act's are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
6	√	√	√	√	√	√	√1	√2	√	√3	√	√
7	√	√	√	√	√	√	√1	√2	√	√3	√	√
10	√	√	√	√	√	√	√1	√2	√	√3	√	√
24	√	√	√	√	√	√	√1	√2	√	√3	√	√
64	√	√	√	√	√	√	√1	√2	√	√3	√	√
147	√	√	√	√	√	√	√1	√2	√	√3	√	√

1. Monitoring frequencies for critical control points were not addressed adequately in the written HACCP plan.
2. Corrective actions that has to be followed in response to any deviation from a critical limit at a critical control point were not addressed adequately in the written HACCP plan.
3. Verification procedures and the frequencies with which these procedures will be performed, were not addressed adequately in the written HACCP plan.

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1. Flow diagram	2. Hazard analysis	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. act's are described	9. Plan validated	10.Adequate verific. procedures	11.Adequate documentation	12. Dated and signed
5	√	√	√	√	√	√	√1	√2	√	√3	√	√
46	√	√	√	√	√	√	√1	√2	√	√3	√	√
62	√	√	√	√	√	√	√1	√2	√	√3	√	√

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. Species sampled	5. Sampling at the req'd freq.	6, Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
6	√	√	√	√	√	√	√	√	√1	√
7	√	√	√	√	√	√	√	√	√	√
10	√	√	√	√	√	√	√	√	√	√
24	√	√	√	√	√	√	√	√	√	√
64	√	√	√	√	√	√	√	√	√	√
147	√	√	√	√	√	√	√	√	√	√

1. Establishment 6, that the method for sponging carcasses for *E. coli* sampling was used, while excision samples criteria was being used for the evaluation of test results.

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. Species sampled	5. Sampling at the req'd freq.	6, Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
5	√	√	√	√	√	√	√	√	√	√
46	√	√	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√	√	√

Attachment D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
6	√	√	N/A	√	√	√
7	√	√	N/A	√	√	√
10	√	√	N/A	√	√	√
24	√	√	N/A	√	√	√
64	√	√	N/A	√	√	√
147	√	√	N/A	√	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
5	√	√	N/A	√	√	√
46	√	√	N/A	√	√	√
62	√	√	N/A	√	√	√